process or is used in a commercial process, and (iv) the defendant was acting in good faith.

11. A faster patent office; more fees, examiners, judges, and branch offices. The AIA increased PTO fees and gave fee-setting authority to the PTO. The PTO is proceeding to hire between 1,000 and 2,000 new examiners, within the next 12 months, to cut down the unprecedented delay in processing patent applications. (The PTO currently has about 5,000 examiners, so that would represent an increase of up to 40 percent.) Furthermore, the PTO is advertising for 100 new judges for the PTAB (Patent Trial and Appeal Board), to deal with the anticipated new load of IPRs and PGRs. Also, the PTO is proceeding with plans to set up its first three branch offices outside of Washington, DC. The new "mini-bus" appropriations bill recently passed by Congress allows the PTO to access all the fees it collects for FY2012, which should finance these expansion efforts, at least in part.
12. Prohibition of human organism patents;
13. Virtual patent marking is facilitated and some false marking cases are inhibited;
14. Best mode is eliminated as a grounds for invalidating a patent; although, oddly, best mode is not otherwise eliminated as a patent requirement.

The Devil in the Details: Stay Tuned for New Rules

The next 12 months will provide further insight into how the AIA will affect patent practices as the PTO adopts new rules to implement the various sections of the AIA. The devil is in the details and, to be sure, there will be plenty of details. We can provide upon request a complete copy of the AIA, or a more detailed executive summary of the act's provisions.

Stephen C. Glazier (Washington, D.C.)
stephen.glazier@klgates.com

Labor Unions Gain Support Through Administrative Actions

During the 2008 presidential campaign, then-candidate Barack Obama pledged his continued support for the Employee Free Choice Act (EFCA), a bill he had co-sponsored in the Senate. The EFCA would have made it easier for labor unions to organize private sector workforces in the United States by, among other things, allowing unions to be certified as the exclusive bargaining representative of a workforce based on authorization cards presented by the union and without the need for a secret ballot election. The EFCA was controversial and met with stiff resistance in Congress. In a question-and-answer session on September 13, 2010, President Obama stated that while his administration continued to support the EFCA, its likelihood of passage that term was "not real high," since, "[f]rankly, we don't have 60 votes in the Senate" to pass it. Instead, President Obama told the group that his administration was trying to do "as much as we can administratively to make sure that it's easier for unions to operate and that they're not being placed at an unfair disadvantage." In other words, what the Obama administration was unable to accomplish through the legislative process it was attempting to accomplish administratively.

Since the president gave those remarks in September 2010, the National Labor Relations Board (NLRB or Board), the agency that administers federal law governing private sector employer-union relations in the United States, has taken a number of unprecedented steps in apparent fulfillment of this directive to make it easier for unions to organize employees.

Proposed Rulemaking to Speed Up Elections

One way the Board has attempted to promote private sector unionization is through a proposed rule designed to speed up the secret-ballot election process. The NLRB allows a union to become the exclusive representative of a group of employees only upon a showing that a majority of the employees in an appropriate unit wish to be represented by that union. The process by which the NLRB determines majority support normally begins when a union files a petition with the NLRB. After an investigation, the Board's regional office conducts a secret ballot election to determine if a majority of employees in the unit wish to be represented by the union. In cases where parties do not agree on terms of the election, the Board's regional office will conduct a pre-election hearing and, if necessary, conduct a post-election hearing to resolve challenges to voters or objections to the conduct of the election.

On June 21, 2011, the NLRB proposed a rule that would dramatically shorten the time between the filing of a union's election petition and the election by curtailing the ability of employers to be heard on pre-election and post-election disputes. Current Board procedures provide for no strict time periods in which hearings on such disputes must be conducted, because the scope and complexity of the issues involved will vary from case to case. However, the proposed rule would require the Board's regional directors to set a pre-election hearing to begin seven days after the hearing notice is served, and a post-election hearing to begin 14 days after the tally of ballots. The proposed rule also would limit the ability of employers to obtain administrative review of disputed pre-election and post-election rulings by the regional director.

The Board's only Republican member, Brian Hayes, sharply dissented from the proposed rule. He cited the Board's expeditious performance in most representation cases and noted that delays were the exception rather than the norm. In fact, for fiscal year 2010, the median time to proceed from the filing of the petition to the election was 38 days (below the Board's target of 42 days), and more than 95 percent of all initial representation elections had been conducted within 56 days of the filing of the election petition (surpassing the Board's target of 90 percent). However, Hayes argued that "by administrative fiat in lieu of Congressional action, the Board will impose organized labor's much sought-after 'quickie election' option, a procedure under which elections will be held in 10 to 21 days from the filing of the petition." He expressed the concern that the change would effectively deprive employers of a legitimate opportunity to express their views to employees about unionization prior to an election.

The NLRB's proposed rule also met with opposition in Congress. On November 30, 2011, the U.S. House of Representatives passed a bill that would effectively block the proposal. Among other things, the bill would require that no union election take place in fewer than 35 calendar days after the filing of an election petition. The bill would also provide that the first election hearing not take place until at least 14 calendar days after the filing of the petition.

The NLRB has not given up on its proposed rule. On November 30, 2011, the same day that the House bill was passed, the NLRB voted 2-1 (with Hayes again dissenting) to approve a resolution adopting a scaled-back version of its original proposal. The scaled-back version, scheduled to take effect on April 30, 2012, will limit the ability of employers to file pre- and post-election challenges to disputed rulings by the regional director but will not incorporate those portions of the original proposal that would shorten the election process. Nonetheless, the scaled-back version is the subject of a lawsuit filed by the U.S. Chamber of Commerce seeking to block its implementation.

Aggressive Pursuit of Injunctive Relief

The Board is also promoting private sector unionization through its aggressive pursuit of injunctive relief in organizing campaigns. Section 10(j) of the National Labor Relations Act authorizes the Board to petition a United States District Court for injunctive relief upon issuance of an administrative complaint alleging that an unfair labor practice has occurred. Historically, the NLRB has exercised its discretion to seek Section 10(j) relief sparingly, generally reserving petitions for such injunctions only for extraordinary cases. However, on September 30, 2010, the acting general counsel of the NLRB announced a new initiative to pursue Section 10(j) injunctive relief in all cases in which the NLRB contends that an employee was unlawfully discharged during a union organizing campaign. This change in enforcement policy has been accompanied by a marked increase in Section 10(j) actions. Whereas the NLRB filed a total of 86 Section 10(j) petitions for injunctive relief for the four-year period covering fiscal years 2007 to 2010 (an average of 21.5 per year), it filed a total of 45 such petitions in fiscal year 2011 alone. With this change in enforcement policy, the Board is now wielding its considerable power to seek Section 10(j) injunctive relief in further support of union organizing campaigns.

New Posting Requirements

The Board is also advancing union activity through a new posting requirement. Now scheduled to be effective on April 30, 2012, this rule is facing several legal challenges, including a suit by the U.S. Chamber of Commerce. If it survives, most private employers will be required to post a notice advising employees of their rights under the National Labor Relations Act. Among other things, the notice advises employees of their right to (1) organize a union; (2) form, join, or assist a union; (3) bargain collectively through representatives of their own choosing for a contract setting wages, benefits, hours, and other working conditions; (4) discuss union organizing, wages, and other terms and conditions of employment with co-workers or a union; (5) take action with co-workers to improve working conditions by raising complaints with the employer or a government agency and seeking assistance from a union; (6) strike or picket, depending upon the purpose or means of the strike or picket; and (7) choose not to do any of the above. The notice also advises employees that it is illegal for the employer to prohibit them from talking about a union during non-work time or distributing literature during non-work time in non-work areas. Similarly, it states that it is illegal for a union to threaten or coerce them to gain support.

The notice must be posted in a conspicuous place where other notices are displayed. It must also be linked to any internal or external website where other notices are posted.

Conclusion

The Democratic-controlled NLRB has taken a number of steps in apparent fulfillment of the president's directive to make it easier for labor unions to organize workers. It has proposed rules that would dramatically speed up the secret-ballot election process; it is aggressively pursuing federal court injunctions where unfair labor practices have been alleged in union organizing campaigns; and it has imposed a new posting requirement. These and other actions by the NLRB pose significant challenges for private sector employers in the United States seeking to resist union organizing in their workplaces. The transformation of the NLRB from an impartial enforcer of national labor law into an advocate for unionization will likely continue, and perhaps intensify, until after the 2012 election.

Rosemary Alito (Newark)
rosemary.alito@klgates.com

George P. Barbatsuly (Newark)
george.barbatsuly@klgates.com

Proposed Reform of UK Employment Law

As part of its continuing efforts to kick-start the economy, the British government has turned its attention to employment law reform. Some of its proposed changes have been promised for some time, but others are new. The aim is to provide employers with more protection and more flexibility in their dealings with employees, to redress the perceived imbalance between the rights of employers and employees, and to instill businesses with a new level of confidence. The proposals have met with predictable levels of support from employer bodies and criticism from unions.

The government's proposals were announced by Business Secretary Vince Cable in a speech to the Engineering Employers' Federation on November 23, 2011. On the same day, in a three-pronged approach to the reform of employment law, the government announced its written response to the *Resolving Workplace Disputes* consultation on the reform of the employment tribunal system, and two "calls for evidence," in which the government invites comments on how legislation is operating in practice, relating to the possible reform of collective redundancy consultation and the UK's legislation which protects employment rights on the transfer of a business (TUPE).

The government's proposals include the following:

- A requirement for all employment litigation claims to be submitted to ACAS, the independent conciliation service, before the claim can begin. This is to allow the parties to undertake a pre-claim conciliation process, if both agree to do so. The parties will have a one-month period in which to attempt to settle the claim, failing which the employee will then be free to commence legal proceedings;
- The introduction of the concept of "protected conversations," to allow employers to raise workplace issues "in an open way, free from the worry it will be used as evidence";
- A thorough review of the employment tribunals' rules of procedure to be carried out by the current president of the Employment Appeal Tribunal, Mr. Justice Underhill. In addition, the government has already announced an increase on the limit applicable to orders imposing court costs (which can be made against either party) from £10,000 to £20,000. The government has also announced that employers who are unsuccessful in their defense of claims may, at the discretion of the employment tribunal, be required to pay a financial penalty to the government of 50 percent of the amount of damages awarded to the employee, subject to a maximum ceiling of £5,000. The penalty will be reduced by 50 percent if paid within 21 days;

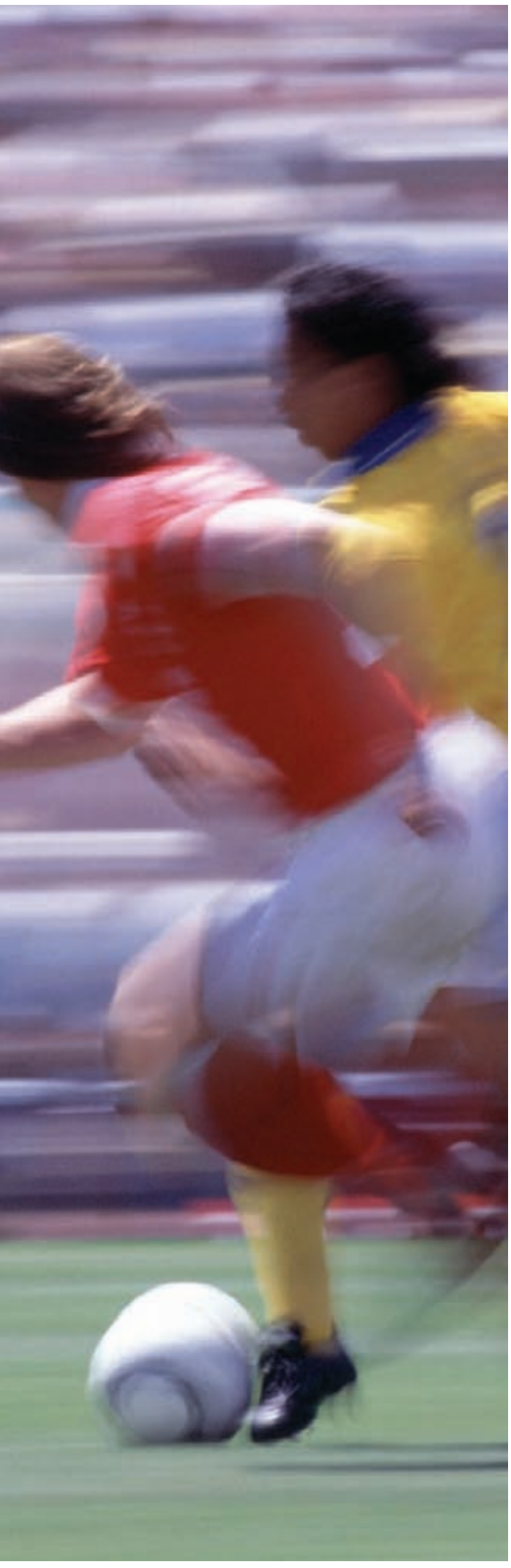
- For the first time, a requirement for employees to pay a fee in order to commence an employment tribunal claim, possibly with higher fees for higher value claims;
- A limitation on the scope of the UK's whistleblowing legislation by overturning case law that has established that employees are entitled to whistleblower protection for complaining about a breach of their own contracts of employment;
- Doubling the service period required before employees can claim unfair dismissal, from one year to two years;
- Simplifying recruitment by reviewing the extensive legislation that governs employment agencies, including a commitment to review in early 2013 the Agency Workers Regulations 2010, which give agency workers the right to be paid at the same level as comparable employees after 12 weeks' employment, and which only came into force on October 1, 2011; and
- Extending to all workers the right to request flexible working schedules (thereby removing the current six-month service requirement) and implementing a more modern system of parental leave which reflects the greater involvement of modern fathers in childcare.

In terms of timing, the government has committed to increase the unfair dismissal qualifying period by April 2012 and has invited Mr. Justice Underhill to recommend a revised procedural code for employment tribunals by that date. Implementation of the government's remaining proposals will be the subject of further consultation.

Critics of the proposals point to the fact that the most concrete of them, the increase in the unfair dismissal qualifying period, will not elevate business confidence as is suggested—especially in times of deep uncertainty created by the Eurozone crisis. The government's own estimates tend to support that view. These estimates state that increasing the qualifying service period will only reduce the number of unfair dismissal claims by between 1,600 and 2,400 each year. Since 47,900 such claims were heard by employment tribunals last year, it is indeed questionable whether a 4 percent reduction will have any practical impact. What is clear is that British businesses will have to come to grips with yet another raft of employment-related legislation, just as they have in previous years under previous governments.

Paul Callegari (London)
paul.callegari@klgates.com

(Sports) Right-Holders At The Crossroads?



The current European sports broadcasting model, which is largely based on separate exclusive licenses for the territory of different EU member states, has been put to the test before the Court of Justice of the European Union (CJEU)—and the enforcement of absolute territorial exclusivity has been found contrary to EU law. In the light of the Murphy/QC Leisure judgment of October 2011, sports right-holders around the world and sports broadcasters in the European Union are currently re-assessing their business models.

The Murphy Case

The case concerned the licensing practice of the English Football Association Premier League (Premier League) for satellite TV broadcasting rights. The Premier League granted exclusive licenses to broadcast live football matches on a territorial basis. Licensees were obliged to prevent their broadcasts from being viewed outside their respective broadcasting areas in order to protect this territorial exclusivity. Satellite signals were therefore encrypted and transmitted only to subscribers within assigned territories: subscribers could decrypt the signal using a decoder card. The license agreements obliged licensees to prevent the circulation of authorized decoder cards outside the respective licensee's territory, with the intention of preventing EU consumers from watching matches via satellite services originating elsewhere in the European Union.

The CJEU dealt with these issues under copyright, competition, and primary EU law. On the copyright aspect, the CJEU stated that sporting events as such were not protected under the Copyright Directive, although they might potentially be worthy of comparable protection under national laws. The CJEU did state that the Premier League would have copyright in at least part of the broadcast of matches (*e.g.*, the Premier League anthem). However, the CJEU did not address the issue of the copyright in the broadcast itself (rather than in the match), which would typically vest in the broadcaster and be assigned back to the Premier League under the license agreement.

The decisive question for the CJEU was on the relationship between copyright law (allowing for territorial or personal restrictions on licensing) and the goal of competition and free movement of services within the internal market. For the satellite broadcasting sector, the CJEU came to the conclusion that the restrictions of competition and of free movement of services in the case at hand could not be justified by copyright law. The *additional* obligations on the broadcasters not to supply decoding devices for use outside "their" territory created an *absolute* territorial exclusivity which was contrary to EU law.

It is important to note, however, that according to the CJEU, the mere fact that a right-holder grants an exclusive right to broadcast protected content in a member state to a sole licensee, and consequently prohibits its transmission by others during a specified period, does not *per se* infringe EU (competition) law. What was considered contrary to EU law (as not necessary for the protection of the intellectual property rights) were the additional obligations aiming at absolute partitioning of national markets along member states' borders.

The CJEU concluded that the restrictions of competition and of free movement of services not be justified by copyright law.

Conclusion

The CJEU did not outlaw exclusive territorial licenses as such. The negative assessment was mainly founded on the additional protection granted through the restrictions on import and export of decoders, which led to an absolute territorial protection designed to prevent any cross-border provision of services. As Michel Barnier, EU commissioner for the internal market, commented on the decision: "*It does not mean that right-holders are obliged to grant licenses for the whole of Europe, nor that broadcasters are obliged to buy a pan-European license.*" But, in the satellite broadcast sector, which is harmonized at the European level and in which licenses are not *per se* limited to a certain destination territory, the absolute territorial restrictions and their protection went beyond what was necessary for the protection of the content protected by intellectual property rights.

For other means of transmission, the judgment is only of limited relevance, as the CJEU's findings are narrowly based on the facts of the case, in particular on the harmonized rules of the Satellite Broadcasting Directive. For cable, IPTV, or internet transmission, no such harmonized rules exist—yet. However, the European Commission has in its communication "A Single Market for Intellectual Property Rights" (May 2011), made it clear that a true single market for intellectual property is the goal. In addition, the commission is currently studying the "economic potential" of the cross-border market in pay TV and is expected to launch a consultation on the audiovisual sector "soon." Thus, irrespective of the *Murphy* judgment, sports right-holders as well as other industries dependant on copyright protection (music, TV, etc.) should remain ready to rethink their business models in the future.

Dr. Annette Mutschler-Siebert, M.Jur. (Berlin)
annette.mutschler-siebert@klgates.com

Dr. Tobias Bosch (Berlin)
tobias.bosch@klgates.com

Dr. Martin von Albrecht (Berlin)
martin.albrecht@klgates.com

Warren L. Phelops (London)
warren.phelops@klgates.com

Andrew R. Danson (London)
andrew.danson@klgates.com

Online Gambling in the European Union: Was 2011 a Landmark Year?

2011 may prove to have been a turning point in the regulation of online gambling in Europe.

Until now, the European Union's institutions (with the exception of the Court of Justice of the European Union (CJEU)) have been reluctant to intervene in an online gambling market which has become increasingly divided along national boundaries. The 27 EU member states have differing cultural, legal, and fiscal approaches to the online gambling industry—some support a state-sponsored gambling monopoly operator, while others have opened their markets to licensed operators within a regulated framework. However, even these national regulated frameworks vary enormously, and the principle of mutual recognition of licensed operators from other member states is rarely applied.

As a result, online gambling operators providing cross-border services in Europe must navigate an inconsistent patchwork of regulated, gray, and restricted markets. Further, the CJEU has had to deal with a stream of cases concerning the conflict between the restrictive online gambling laws of many member states on the one hand, and the freedom to provide services enshrined in the Treaty on the Functioning of the European Union (EU Treaty) on the other.

However, 2011 has seen the European Commission publish a green paper on online gambling, and the European Parliament issue an own-initiative report on the topic.

European Commission Green Paper

In 2011, the European Commission's green paper on online gambling launched a public consultation covering the regulation of gambling and related services (including advertising and sponsorship) in Europe, enforcement, and public policy issues.

That consultation closed in July 2011, and the commission is now considering the responses. It is unclear what the next steps will be: it may be that the consultation is followed by a white paper setting out policy options influenced by the information gathered, and, perhaps, a legislative proposal thereafter. However, it seems extremely unlikely that the market will be harmonized, or even that member states will be prepared to adopt a policy of mutual recognition toward gambling operators established in other member states. Any such developments would require the support of member states who, until now, have rarely reached agreement on the topic. However, as described below, the commission has now been given some clear guidance by the European Parliament.

European Parliament Report

On November 15, 2011, the European Parliament adopted its own report on online gambling in the internal market (the Creutzmann Report).

Given that the member States differ greatly on this issue, it is no surprise that the Creutzmann Report rejected legislative uniformity within the internal market and supported the discretion of individual member states to make their own gambling policy, so long as it is proportionate and non-discriminatory.

Nevertheless, the report still represents a change of direction from the European Parliament in favor of the regulated online gambling industry and demonstrates a new emphasis on cooperation between member states and upholding EU Treaty principles in the sector. Importantly, the report urges the commission to take a more active role to pursue infringement proceedings, to uphold EU Treaty principles in favor of EU-licensed operators, and to consider introducing common standards and a framework directive.

The report represents a change of direction in favor of the regulated online gambling industry.

It is also particularly interesting that the Creutzmann Report recommends that a controversial property right for sports event organizers, along the lines of the "fair return" mentioned in the commission's green paper, should be recognized. While that is merely a recommendation, if implemented it could mean that sports organizations would be able to charge gambling operators for the privilege of taking bets on their events.

Conclusions

It is welcome that both the European Parliament and the European Commission have decided that this issue could benefit from some central policy guidance. What happens next is less certain: the Creutzmann Report is non-legislative, and the timing and the nature of the next steps from both the European Parliament and the commission are unclear. With such divergent attitudes towards the regulation of gambling among member states, it will be difficult to forge any real progress in the short to medium term.

At the same time, the tide may be turning against the state-sponsored gambling monopoly model in the European Union—at least where member states' gambling policies can be shown to be inconsistent, discriminatory, or disproportionate. We may also see a greater degree of legal certainty for the industry in the future, and increased cooperation between regulators in different member states.

The events of the next few years promise to be just as significant as the one just past.

Warren L. Phelops (London)
warren.phelops@klgates.com

Andrew R. Danson (London)
andrew.danson@klgates.com

Filtering Policies and Gambling Regulation in Europe: The CJEU Applies Net Neutrality Principles

After almost a decade of vigorous debate among interested parties, the Court of Justice of the European Union (CJEU) has finally issued a decision that moves toward unifying the European perspective on internet filtering. While the CJEU decision itself is specific to the gambling industry, the core principles of the decision may be extended to other fields.

Several recent decisions by the CJEU put into a strict perspective the validity of the position held by certain European member states with regard to gambling, namely state-sponsored monopolies [see for instance CJEU case C-42/07]. At the same time, the opening of the online gambling field to authorized operators in European countries, such as France, went hand-in-hand with the creation of administrative agencies. Those agencies, such as France's Autorité de Régulation des Jeux en Ligne (ARJEL) possess, among other things, the prerogatives and powers to demand the take-down of cross-border gambling and gaming websites deemed illegal under national law and accessible by individuals connecting from the same country.

On the other hand, on the copyright and peer-to-peer front, collective rights management agencies have been heavily involved in regulating the contents made available on the Internet. Indeed, for the past decade since the appearance of Napster, right-holders have been trying relentlessly to limit the impact of online copyright infringement, by pursuing action against individual downloaders in the first place, and then against the website publishers making illegal content accessible.

On both fronts, though, the temptation for grasping control over Internet content can be seen lingering around.

In the *SABAM vs. Scarlet* decision (CJEU case C-70/10), published on November 24, 2011, the CJEU applied a five-prong approach on Internet control ordered by third parties on Internet Service Providers (ISPs) that may be extended to the gaming and gambling industry. In SABAM, the Belgian collective rights management entity had requested ISPs to cut access to several websites that allowed the illegal download of copyrighted material.

Although the national laws of EU member states specify the requirements for obtaining an injunction against the operator of an online service deemed illegal, such as national law must be compliant with the mandatory limitations set forth by European law, notably in the e-Commerce Directive 2000/31/EC. The e-Commerce Directive provides in Article 15.1 that "*Member states shall not impose a general obligation on providers, when providing the services covered by Articles 12, 13, and 14, to monitor the information which they transmit or store, nor a general obligation actively to seek facts or circumstances indicating illegal activity*." This has been understood by many commentators as the founding European net neutrality principle.

As a consequence of this European net neutrality principle, national authorities may not adopt measures which would require an ISP to carry out general monitoring of the information that it transmits on its network.

In the SABAM decision, the Belgian courts requested that the CJEU clarify whether European law would permit an injunction that would require an ISP to implement a filtering system for all electronic communication transiting through its services where such filtering would:

- Apply impartially to all of the ISP clients;
- In a preventive manner, as opposed to a reactive manner where infringing content, once identified and notified by the right-holders, would be dealt with;
    - In a permanent manner, as opposed to a temporary measure; and
    - At the sole costs of the ISP.

Following its advocate-general, who had concluded in the preceding legal opinion that this scheme was obviously disproportionate with regard to the rights to be protected, the court held that the implemented measures have to be "*fair and proportionate and must not be excessively costly.*"

Additionally, the court foresaw the practical consequences of such general filtering and blocking—the ISPs need to appreciate the legality of the online services, which would thus "*require active observation of all electronic communications conducted on the network of the ISP concerned and, consequently, would encompass all information to be transmitted and all customers using that network*." In other words, instead of relying on an evidenced take-down request from the right-holders, such right-holders were requesting that the ISPs themselves perform all the necessary checks on all the material they make available to ensure no infringing content would be available. At the same time, such a measure would have been in complete contradiction with the founding principle of Article 15 of the e-commerce directive and the net neutrality principle.

Moreover, the court drew attention to the fact that to permit the ISP to be the judge of what internet content was to be deemed illegal would likely adversely affect freedom of expression by blocking, albeit in a collateral manner, legal services and information. According to the court, the ISP bears a technical role in the individual's access to the Internet. Therefore, its involvement should be limited to such a technical role, except in cases where the obviousness of the illegality of the targeted content prevails.

Finally, to the great satisfaction of many privacy advocates, the court seized the opportunity to state incidentally that the IP addresses used for ISP subscribers' identification purposes were personal data. Indeed, in spite of the strict regulation of personal data processing in Europe, many national laws of agencies, in order to implement fast proceedings against illegal online file-sharing, were quick to dismiss the need for compliance with data protection law. This latest observation also calls for moderation in the processing of online data and information, be it by right-holders, collective rights management organizations, or administrative agencies all over Europe.

Claude-Étienne Armingaud (Paris)
clawdey.armingaud@klgates.com

Etienne Drouard (Paris)
etienne.drouard@klgates.com

U.S. Supreme Court to Decide Future of Health Care Reform Act

In November 2011, the United States Supreme Court announced that it will hear three petitions arising from a decision of the Eleventh Circuit Court of Appeals regarding the Patient Protection and Affordable Care Act (the Act). The Act is the comprehensive federal health reform law, which was signed into law by President Obama in March 2010. The three petitions were filed by: (1) the State of Florida and 25 other states, (2) the National Federation of Independent Business, and (3) the federal Department of Health and Human Services, the Department of the Treasury, and the Department of Labor and their respective Secretaries.

The Supreme Court will address the following issues:

- Whether parties are prevented from challenging the Act's mandate that virtually all individuals obtain minimum health insurance coverage (the "individual insurance mandate") because of the Anti-Injunction Act (AIA). *The Eleventh Circuit did not address this issue but other courts have, resulting in conflicting opinions, so the federal government requested that the Supreme Court consider the issue.*
- If parties are not barred by the AIA, whether the individual insurance mandate is unconstitutional as exceeding Congress's powers under Article I, Section 8 of the U.S. Constitution (the Commerce Clause). *A majority of the Eleventh Circuit held that the individual insurance mandate exceeded Congress's Commerce Clause power, and that Congress did not pass the legislation under its taxing authority.*
- If the individual insurance mandate is unconstitutional, whether the provision is severable from the remainder of the Act. *The Eleventh Circuit reasoned that precedent favors severing the unconstitutional provision and allowing the remainder of the Act to remain in place.*
- Whether the provisions in the Act to expand the Medicaid program are unconstitutional. *The Eleventh Circuit upheld the expansion provisions.*

The Individual Insurance Mandate and the AIA

The AIA bars lawsuits seeking to enjoin the assessment or collection of a *tax*. Under the Act, individual taxpayers who for three consecutive months fail to purchase the required minimum insurance coverage must pay a "penalty." This penalty provision is contained in the tax code and is payable through the individual's tax return. However, the provision is labeled a "penalty" rather than a "tax." The Supreme Court will determine whether the individual insurance mandate is in fact a tax. If so, the AIA would apply and the Supreme Court would lack jurisdiction to consider the challenges to the individual insurance mandate.

The Constitutionality of the Individual Insurance Mandate

The Commerce Clause empowers Congress to regulate commerce among the states and within the states when such activity has a "substantial effect on interstate commerce." Courts examine challenges to Commerce Clause-based legislation using a rational basis test. The focus of the review is whether there is an appropriate and reasonable connection between the means (*i.e.*, the regulatory scheme) and the ends (*i.e.*, the goals to be accomplished by the legislation).

The Supreme Court will examine whether the individuals who choose not to purchase insurance nevertheless are participants in the health insurance and health services market that is regulated by the Act, and therefore, are engaging in interstate commerce. The parties will ask the court to decide also whether the individual insurance mandate is a necessary means to obtain the goals of availability and affordability of health insurance and health care for most Americans.

The federal government is also asking the court to evaluate the legality of the individual mandate under Congress's power to tax, raising issues that are similar to the AIA issue described above.

The Severability of the Individual Insurance Mandate

The individual insurance mandate appears at section 1501 of the Act, and is codified in the Internal Revenue Code. It is one of hundreds of sections in a complex act that for the most part is structured toward achieving the goal of health care coverage for most Americans at an affordable price. The Supreme Court will reach the severability issue only if it determines that the individual insurance mandate is unconstitutional. If it makes that determination, it will need to decide whether any other provisions are so entwined with the mandate that they cannot be severed from the Act and thus also must be struck down.

The Constitutionality of Medicaid Expansion

The Supreme Court also will consider whether the expansion of the Medicaid program that is required of states participating in the program is within Congress's authority under the Spending Clause of the U.S. Constitution. Congress uses the Spending Clause to authorize payment of federal funds to states, with strings attached. The statute establishing the Medicaid program is Spending Clause legislation, meaning that the program is voluntary, but once a state elects to participate and draw down federal funds, it must comply with the rules attached to the funding. The court will decide whether the federal requirements to expand coverage of the program render it coercive rather than voluntary, since the "amount of funding at stake is unprecedented" and Congress is attaching new conditions to existing funds, not just to the new funds.

Possible Outcomes

The case raises multiple constitutional and legal questions with a range of potential outcomes. If the court holds that the individual insurance mandate is a tax, the AIA would bar the court from considering the constitutionality of the mandate.

If the court determines that the AIA does not bar it from considering the individual insurance mandate, the court could find that Congress exceeded its enumerated powers and strike down the individual mandate.

If the court strikes down the individual insurance mandate, the court could:

(1) decide that the mandate section is wholly severable and strike only that provision;

(2) find the mandate is partially severable but so entwined with certain other provisions that also must fall with the mandate, the intricacies of which could be decided by the Supreme Court or by remand to a lower court; or

(3) strike the entire Act because the mandate cannot be severed from the Act.

On the other end of the spectrum, the court could find that the individual insurance mandate is constitutional. The Medicaid expansion would be considered separately, and if also found constitutional, the entire Act would remain in effect.

Ruth E. Granfors (Harrisburg)
ruth.granfors@klgates.com

Patricia C. Shea (Harrisburg)
patricia.shea@klgates.com

New EU Food Labeling Law Requires Clarity of Consumer Information

The EU's new Food Information Regulation (FIR) came into effect on December 12, 2011. The FIR sets out labeling requirements for nutritional and country of origin information on foods intended for retail consumers. The FIR represents a considerable change from prior requirements for food labeling. It combines and updates Directive 2000/13, on labeling, presentation, and advertising of foodstuffs, and Directive 90/496, on nutrition labeling for foodstuffs, and adding new requirements on food labeling.

For most of the new provisions, there is a three-year transitional period for importers and producers to comply, and a five-year period for the application of mandatory nutrition declaration requirements.

Food Information

Among other things, the FIR introduces mandatory nutrition labeling for most processed foods, including information on the energy value, amounts of fat, saturates, carbohydrates, protein, sugars, and salt. Information must be presented in a single, clearly legible table on the packaging, and expressed as amounts per 100ml or 100g. Provisionally exempted from this requirement are alcoholic beverages containing more than 1.2 percent by volume of alcohol, and unprocessed foods contained in packaging too small to accommodate mandatory labeling requirements (less than 25cc). A product, irrespective of its size, must also display information about its name, whether certain allergens are contained in the product, its net quantity, and the date by which it must be consumed. Regarding the exemption for alcoholic beverages, the commission must revisit the new regulation within three years and address whether mandatory nutrition information should apply for alcoholic beverages in the future. Producers of pre-packaged food will have to adjust contents and layout of labels to the additional information required. If pre-packaged food is sold by internet or mail order, sellers will also have to make available all mandatory information in advance of the sale, *e.g.*, on the related webpage or catalog entry.

Requirements for country of origin labeling have been extended. Previously, origin marking was obligatory only for certain foods such as beef, honey, and olive oil. The FIR now requires country of origin labeling for most meats, including fresh meat from pigs, sheep, poultry, and goats, as well as additional food categories, *e.g.*, dairy products. The commission is obliged to develop specific rules for mandatory labeling of meat within two years, and is even authorized to extend the country of origin labeling further on other types of meat, milk, single-ingredient products and ingredients that represent more than 50 percent of a food.

The FIR strengthens previous provisions on the identification of potentially allergenic substances, requiring that this information be provided not only on prepackaged foods, but with regard to all foods. EU member states are authorized to decide the means by which this information should be provided to consumers. Food providers selling non-prepackaged foods, in particular supermarkets, caterers, and restaurants, will need to adapt and train employees in order to ensure compliance with the new requirements.

Fair Information Practices

Complementary to the general prohibition of misleading commercial practices set out in Directive 2005/29 (Unfair Commercial Practices Directive), the FIR generally requires food labeling not to be misleading. This requirement also applies to advertising and the presentation of foods, including the appearance or packaging, the way in which food products shall be arranged, and the setting in which they shall be displayed. Therefore, any pictorial presentations and marketing claims on packaging or advertisements must comply with fair information practices. These practices become particularly important in connection with so-called "imitation foods," which look like natural foods, but substitute different components or ingredients for the natural ingredient. A prominent example is "cheese" made from vegetable oils.

Liability of Food Operators

The FIR contains specific provisions as to responsibility along the food chain regarding the presence and accuracy of food information. Legal responsibility for the food information lies with the food business operator, *i.e.*, the operator under whose name the food is marketed. As the FIR requires the food operator to be listed on the packaging, importers and retailers will have to make sure that the original supplier of a food product is named on the product in order to avoid liability for the accuracy of the presented food information.

Dr. Mathias Schulze Steinen, LL.M. (Frankfurt)
mathias.schulze-steinen@klgates.com

Daniela Bohn (Frankfurt)
daniela.bohn@klgates.com

Traditional Herbal Medicines in the European Union: Is the Herbal Directive a Benefit or Obstacle?

Since May 1, 2011 new rules on marketing authorization apply to certain herbal medicinal products. These rules may have important effects for manufacturers and importers of such products.

EU Directive 2004/24 (the Herbal Directive) amends EU Directive 2001/83 on the Community Code relating to medicinal products for human use as regards traditional medicinal products. Under that directive, herbal medicinal products required an authorization before they could be marketed as such in the EU. Application for a marketing authorization required the submission of an extensive dossier and demonstration of a well-established medicinal use with recognized efficacy. Many traditional herbal medicinal products could not satisfy these requirements and could not therefore be marketed as medicinal products in the EU. Instead, Member States often took the view that they were not "medicinal products" within the meaning of the EU legislation and permitted them to be marketed as food supplements, which are subject to EU legislation on food and can be marketed without registration.

The Herbal Directive introduces a uniform regime for the new category of "traditional herbal medicinal products." This regime is less onerous than that applicable under EU Directive 2001/83 to conventional medicinal products.

What are Traditional Herbal Medicinal Products?

Herbal medicinal products are defined as products which contain exclusively herbal substances or preparations (although vitamins and minerals having an ancillary action may be added). Traditional herbal medicinal products are defined as those that have been in medicinal use for at least 30 years, including at least 15 years in the EU, provided that data demonstrate that use is harmless and efficacy is plausible, are intended and designed to be used without the supervision of a medical practitioner, are exclusively for administration in accordance with a specified strength and dosage, and are prepared for administration orally, externally or by inhalation (rather than by injection).

The Herbal Directive

The Herbal Directive establishes a simplified registration procedure for traditional herbal medicinal products. In contrast to other medicinal products for which a marketing authorization is sought, the application for registration does not need to include pre-clinical tests, clinical trials, a pharmacovigilance summary, or a risk management plan. The applicant must, however, demonstrate that its product satisfies the definition of a traditional herbal medicinal product [see above] and submit:

- bibliographical or expert evidence that the product (or a corresponding product) has been in medicinal use for the requisite period
- a bibliographic review of safety data
- an expert report

The Herbal Directive introduces a uniform regime for the new category of "traditional herbal medicinal products" that is less onerous than that previously applicable to conventional medicinal products.

- evidence that the product was manufactured in compliance with the principles and guidelines of good manufacturing practice as laid down by the commission in EU Directive 2003/94.

The simplified registration procedure is a national procedure. This means that an application must be submitted in each EU member state where the applicant intends to market the product. However, the relevant national authorities will recognize registrations granted by other member states in certain circumstances.

The Herbal Directive also requires that any labeling of a registered traditional herbal medicinal product must state that the product is a traditional herbal medicine and that the user should seek medical advice if the symptoms persist.

Benefits or Obstacles?

Now that traditional herbal medicinal products are tightly defined and regulated in the Herbal Directive, it will be more difficult for Member States to take the view that products falling within that definition can continue to be marketed as food supplements (although herbal products making no medical claims may still be marketed as such). Compared to the formalities for obtaining a marketing authorization for "normal" medicinal products, the new registration procedure for traditional herbal medicinal products will be simpler, quicker and, therefore, less expensive. It is nonetheless expected that some manufacturers and importers will take their traditional herbal medicinal products off the EU market rather than incur the costs of registration. This is likely to be the case in particular for multiple herbal products and for herbal medicinal products that are not based on European traditions, such as Chinese and Ayurvedic medicinal products. Such products often do not have the long history of use within the EU which is necessary for simplified registration under the Herbal Directive. They will therefore require a standard marketing authorization as for all other medicines, including costly and time-consuming tests and clinical trials. Manufacturers will have to calculate from potential sales figures in the EU market whether this is worth the investment and effort.

Daniela Bohn (Frankfurt)
daniela.bohn@klgates.com

Vanessa Edwards (London, Brussels)
vanessa.edwards@klgates.com

Will UK Lobbyists be Required to Register?

It was in October 2011 that the UK Coalition Government faced its second major Cabinet resignation, after less than 18 months in office. (The first Cabinet resignation occurred within two weeks of the Coalition government being formed.) On this occasion, Secretary of State for Defense Liam Fox resigned over his links with his friend and advisor Adam Werritty. Questions were raised about Mr. Werritty's having accompanied Dr. Fox on a number of overseas visits and issuing business cards erroneously suggesting that he had an official advisory position. Those who had funded research bodies set up by Dr. Fox were purportedly unaware that many of their contributions were used to fund Mr. Werritty's own expenses.

Following Dr. Fox's resignation, David Cameron, the British Prime Minister, took the opportunity to repeat his pledge to introduce a mandatory statutory register for lobbyists. Mr. Werritty actually never acted as a lobbyist in this role, so whilst this was a great opportunity to knock lobbyists in general, it actually had no real relevance to the scandal that led to Dr. Fox's resignation.

Lobbyists are easy "knocking fodder" in opposition. All political parties (especially those in opposition) believe in complete transparency. When he was Leader of the Opposition, Mr. Cameron several times pledged to tackle lobbying, stating that it was "*the next big scandal waiting to happen*" and had "*tainted our politics for too long…*" and he wanted politics to "*… come clean about who is buying power and influence.*"

Greater regulation of lobbyists was a manifesto commitment by both governing

Greater regulation of lobbyists was a manifesto commitment by both governing parties and features in the Coalition Agreement.

parties and features in the Coalition Agreement (that was the agreement between the Conservatives and the Liberal Democrats which led to the formation of the Coalition government). The Coalition government planned to introduce a consultation paper on lobbying by the end of November 2011. Latest indications from the Cabinet office are that a consultation paper may materialize in early 2012. Even so, there are many different views about the operation of a mandatory registration scheme, and the prospects are that any legislation is unlikely to come into force until the 2013/14 Parliamentary session.

Lobbyists in the UK have tried to head off statutory-based regulation by setting up their own self-regulating body called the UK Public Affairs Council, an umbrella body consisting of three key industry trade associations. On December 9, 2011 one of those three trade associations withdrew from this body. The UK PAC was intending to establish a voluntary register of interests, but their failure to agree amongst themselves is not at all promising and makes the prospect of statutory regulation all the more likely.

On December 6, 2011 "The Independent" reported a claim by senior officials at a leading UK public affairs agency that they could secure direct access to senior members of the government. Their managing director was recorded as saying "*we've got all sorts of dark arts…he couldn't put them in the written presentation because it's embarrassing if it gets out.*"

It is therefore not terribly surprising that the good intentions behind the establishment of the UK PAC appear to have failed.

What will the new register require? Will it be lobbying firms or individual lobbyists that have to be registered? How do you define a "lobbyist" for these purposes? Will they have to record every single meeting and proposal or will the register be more generic? Will the register have to include law firms? The European Commission and the European Parliament have recently jointly launched their own voluntary register, which might provide the UK government with an interesting model. Whether or not an organization should register depends on whether or not they or their members are involved in "*directly or indirectly influencing the formulation or implementation of policy and the decision-making processes of the EU Institution.*" Registration does bring advantages, such as access to the European Parliament's premises. However, the downside of registration is a requirement to disclose details of annual turnover, resources devoted to lobbying activities, and potentially the names of clients.

In the UK, the terms "lobbyist" and "lobbying" are deeply unattractive and somewhat derogatory of a valued industry that has an important and effective democratic function. As is always the case, it is the actions or statements of a few that cause so much damage to the whole. The government's determination to regulate becomes stronger every time that a consultant claims (with or without any justification) that he can influence those in government (whether national or local). Whether there is actually an appetite within the Coalition government to carry through the statutory register remains to be seen. So much has happened in the last few months, and the UK government seems to have far greater priorities at the moment. Maybe a statutory register will still only be a promise when the political parties are campaigning again at election time in 2015.

Piers Coleman (London)
piers.coleman@klgates.com

Towards a European Market in the Defense Sector?

The EU has been working on the integration of the defense sector into the European internal market for years, the ultimate goal being a level playing field for the defense and security industry in the EU in order to secure a strong defense technological and industrial base. Efforts to reach this aim were intensified since 2003 with the European Commission's communication "*Towards an EU Defense Equipment Policy*." This summer, finally, the so-called "Defense Package" came into force, containing a Procurement Directive and a Transfer Directive.

The Procurement Directive

The Procurement Directive (Directive 2009/81/EC) addresses the coordination of procedures for certain works contracts, supply contracts, and service contracts awarded by contracting authorities or entities in the fields of defense and security. With the Procurement Directive, the EU aims at the gradual establishment of a European defense equipment market. The directive creates a formal framework specifically designed for (generally sensitive) defense procurements, which under the prior framework were often awarded without formal tender procedures. It applies to contracts exceeding an estimated value of over €400,000 for supply and service contracts and over €5,000,000 for works contracts. The Procurement Directive sets up enforceable common rules for the procurement of military equipment and sensitive equipment and is designed to foster, develop, and sustain a European defense technological and industrial base that is capability driven, competent, and competitive.

Additionally, the directive provides for specific exemptions from its scope, *e.g.*, for contracts for intelligence activities or cooperation programs on research and development. It also provides rules concerning subcontracting, the use of electronic auctions, transparency, and most importantly on review procedures allowing bidders to challenge procurement decisions.

Although the EU is aiming at a European market in the fields of both defense and security, the Procurement Directive stresses that the directive's scope ends where national security interests in a member state are at stake: their protection remains the exclusive right and responsibility of each member state in accordance with Article 346 of the Treaty on the Functioning of the European Union (TFEU). As a consequence, the Procurement Directive does not apply when the tender

The Defense Package should make life easier for the very diverse and international defense industry by reducing companies' efforts to deal with different national regulations.

process in itself would be contrary to the protection of certain national interests concerning the core of national security and defense.

The Transfer Directive

The Transfer Directive simplifies the terms and conditions of transfers of defense-related products within the Community. With the Transfer Directive, the EU seeks to harmonize each of the Member State's rules concerning the transfer of defense-related products within the EU. The ultimate goal is to ensure the proper functioning of the internal market in the defense sector. The directive applies to defense-related products as set out in an annex. Under the directive, the intra-community transfer of defense-related products will continue to be subject to prior authorization through general, global, or individual transfer licenses granted or published by the "departure" member state, *i.e.*, the state from which the respective supplier wants to transfer defense-related products. However, the Directive now sets up common European rules for licensing procedures and contains incentives for member states to replace their existing individual licenses with general licenses for intra-community transfers as far as possible. As a result, in the future global licenses, grouping multiple transfers by one supplier to several recipients, is supposed to become the rule and individual licenses the exception. Member states will remain free, though, to determine the products eligible for the different types of license and to fix the terms and conditions of such licenses.

Conclusions

The Defense Package should make life easier for the very diverse and international defense industry by reducing companies' efforts to deal with different national regulations. The Procurement Directive's rules will open up markets to which companies had no access before. Once a contract is put out for tender, every company can at least apply for it, and will win the award if it hands in the best offer. Therefore, the most interesting question will be whether a contract falls under the Procurement Directive's scope and its tender requirement. That will mainly depend on how the awarding authorities will interpret the TFEU exception clause in Art. 346. However, the European Court of Justice, as well as several national courts, have made it clear in the past that this clause has to be interpreted restrictively. As a consequence, the EU's latest steps towards an internal market have a good chance to be successful in creating more competition and transparency in the defense market.

Dr. Friedrich Ludwig Hausmann (Berlin)
friedrich.hausmann@klgates.com

Dr. Annette Mutschler-Siebert, M.Jur. (Berlin)
annette.mutschler-siebert@klgates.com

The United Kingdom's Localism Act 2011

The Localism Act 2011 was enacted in November 2011 and was much vaunted as one of the key pieces of legislation in the UK Government's "Big Society" agenda. "Big Society" is a vaguely described concept bringing together a number of attempts to bring greater liberalism and empowerment to governance and administration in the UK.

When the UK government first announced the publication of the Localism Bill, it said it would "put an end to the hoarding of power within central government and top-down control of communities, allowing local people the freedom to run their lives and neighborhoods in their own way" and "herald a ground-breaking shift in power to councils and communities overturning decades of central government control and starting a new era of people power."

That would be to overstate what the act does achieve, but it does bring change to local government in the areas of local governance, land use planning, and social housing, and has some novel ideas.

There is much speculation as to how significant the impact of these changes will be in practice, as the secondary legislation which will contain much of the detail is yet to be drafted, and the majority of the act is not yet in force.

Governance

One of the provisions that has been heralded as a paradigm shift in local governance is a new general power of competence for local authorities. This is to give local authorities the power "to do anything that individuals generally may do." This would be a huge shift (as it would even allow local authorities to act irrationally and unreasonably), but this headline power is constrained by subsequent limiting provisions in the act that restrict the general power by any current limitations on their power, and hence the headline objective may not be achieved in practice.

Neighborhood Plans

The act grants to local communities a new power to make neighborhood plans. The UK land use system is plan-led, meaning that the policies in those plans are fundamental to whether a development is granted permission or not. Previously plans were written by local authorities at borough, district or unitary level, or by the London mayor. This new plan-making power would be a significant shift of authority down to local communities which could set their own agenda and priorities. Developers fear this power would be used to oppose development.

However, the power is restricted so that only a parish council (or similar designated neighborhood forum where no parish council exists) can make the plan, and that the neighborhood plan must be in accordance with the strategic policies in the development plan (called the Local Plan) made by the local authority. In other words, the neighborhood plan cannot be more restrictive than the Local Plan and national guidance, but it is not known how any conflict in practice will be resolved. Also, the procedure to create a neighborhood plan is convoluted, expensive, and if published, it will add another level of bureaucracy, which is likely to cause confusion.

Community Right to Buy

The act imposes a moratorium period on the private sale of land and buildings that are listed as "assets of community value." These are to be defined by regulations to follow but are considered likely to be leisure uses, buildings and land in community use, cinemas, public houses, open land currently used for recreational and leisure purposes, theatres, car parking, community facilities, and sports facilities. Any owners of an interest in land (irrespective of whether or not they are in the public or private sectors) whose land or property is listed as an asset of community value must notify the local authority of their intention and not enter into a relevant disposal of the land for six weeks, or six months if a bid to purchase is made. The act does not provide a right to buy or provide to whom the asset should be sold, but does give the community an opportunity to make a bid to save a community asset. However, it may impact values, cause delay, and create problems for those seeking to dispose of such assets, including private and local authority-owned assets.

Local Authority Services

The act provides a community right for charities, voluntary bodies, and even employees of the local authority to express an interest in taking over a local authority service. The type of local service is likely to be limited by later regulations. The act does not require the local authority to automatically give over the service, but seeks to limit upon what grounds it can reject an expression of interest. The objective of this provision is to allow local people the opportunity to run services like libraries, but it remains to be seen whether other services will be impacted.

Social (Low Income) Housing

The act makes large changes to social (low income) housing, which traditionally has been more centrally administered than the other aspects of the act. Social housing is intended to move away from a "house for life" to a more limited tenure, allocated according to provisions set by the local authorities. The act will ensure that more financial decisions will be set at the local level to respond to local need. The public sector has undertaken little social housing development in the last few decades, and there may be an opportunity for local authorities to undertake or facilitate such development. The current social housing regulator is being disbanded, and the regulation function changed to a more "reactive" approach. Tenants will be encouraged to form tenant panels to hold landlords to account for failure to provide services. These changes are untested and have received both criticism and praise.

New Development Tax

The provision likely to have the greatest immediate impact is a new development tax called the Community Infrastructure Levy (CIL). The genesis of this tax was from the previous government, which created the framework for CIL in the Planning Act 2008, and which the current act amends. Larger developments currently make financial and other contributions to local authorities in planning obligations that are flexible and able to be negotiated on a case-by-case basis. In the new provisions, each local authority will set a tariff for all new development to pay. The levy must be paid if the proposed development is to go ahead, and there are limited exemptions and little flexibility. The local authorities are just starting to publish their tariffs, and it may mean many developments will become unviable (if the rate of the levy is set locally at too high a level), just when the UK government says it is seeking to encourage development. The tax was conceived to be used on the future development of community infrastructure (transport, education, energy, libraries, open space, etc.). The act allows local authorities to use CIL on the maintenance of current infrastructure, thereby incentivising local authorities to use CIL as a revenue source, rather than as a fund for needed new infrastructure.

Balancing Empowerment and Economic Growth

The UK government is trying to strike a difficult balance between encouraging growth and empowering local communities, and until further regulations are released it is too early to be definitive on the efficacy of the changes. Communications from the UK government herald the act as making ground-breaking changes to end the hoarding of power by central government. The reality of the current situation is not as centralized as made out, and the act and its regulations cannot live up to this level of hyperbole, but it is clear that it will have both positive and negative impacts for the foreseeable future.

Sebastian A. Charles (London)
sebastian.charles@klgates.com

Paul D. Thompson (London)
paul.thompson@klgates.com

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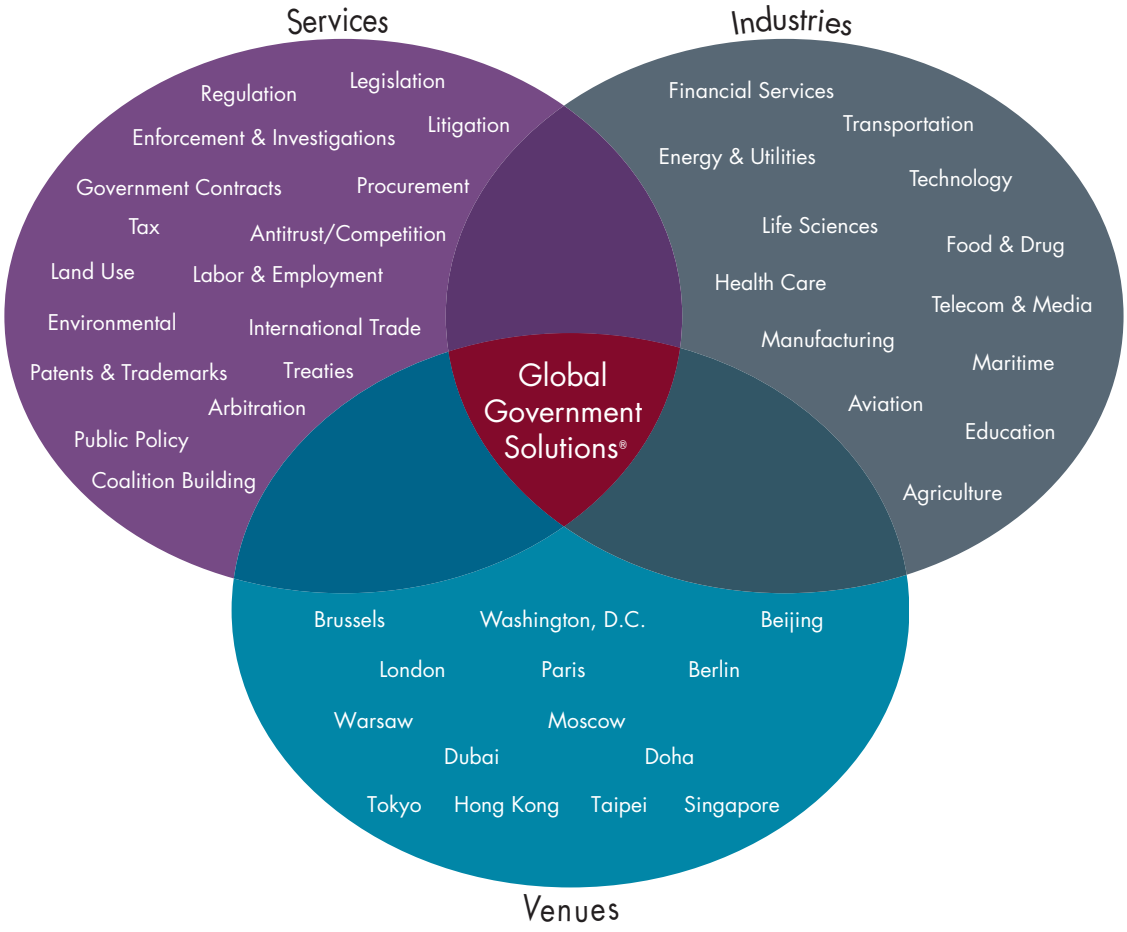

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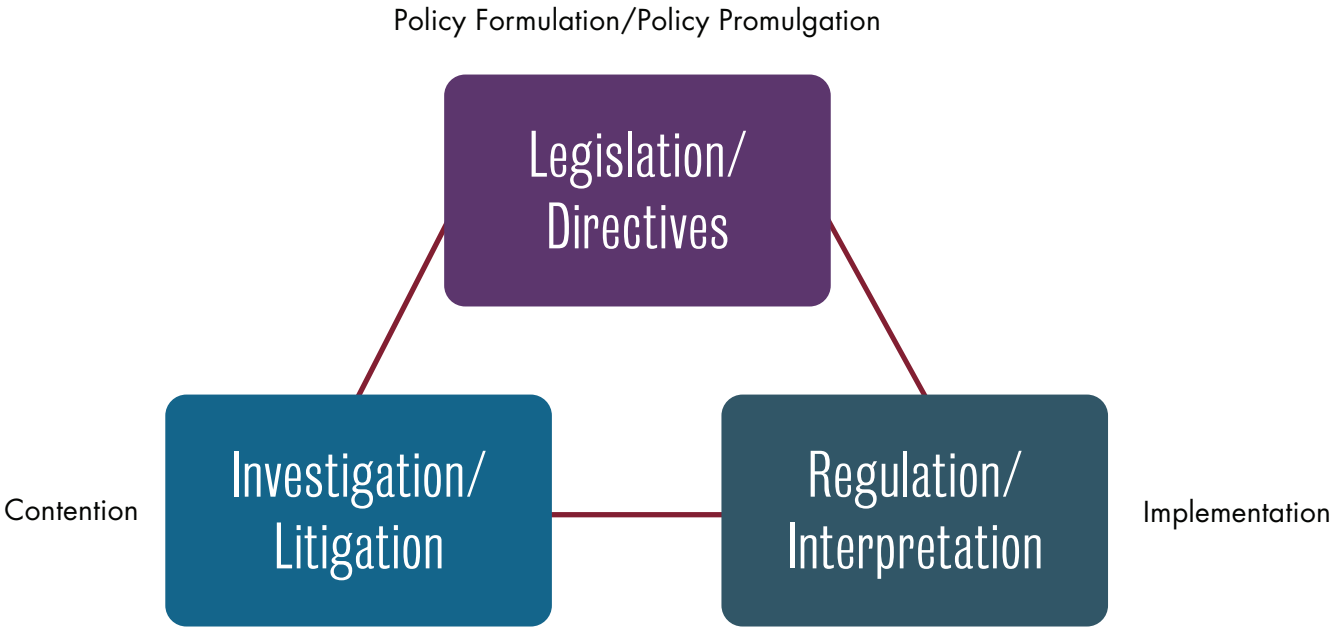

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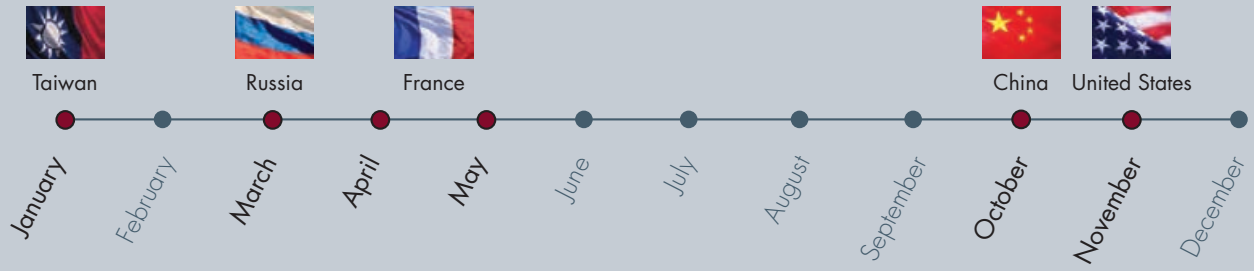

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This directory of our European Regulatory capabilities provides a concise overview of the K&L Gates regulatory lawyers located across Europe. The directory is structured by regulatory practice area, and provides essential information on each lawyer's proven experience within that sector. The objective of the directory is to assist clients looking for a specific capability and to facilitate efficient contact between those clients and the appropriate member(s) of our European Regulatory Group. To download a copy of the directory, please visit our website at klgates.com/EURegulatoryDirectory.

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K&L Gates Locations

Anchorage
420 L Street, Suite 400
Anchorage, Alaska 99501
+1.907.276.1969
Fax +1.907.276.1365

Austin
111 Congress Avenue, Suite 900
Austin, Texas 78701
+1.512.482.6800
Fax +1.512.482.6859

Beijing
Beijing Representative Office
Suite 1009-1011, Tower C1
Oriental Plaza, No.1 East Chang An Avenue
Dongcheng District, Beijing 100738
China
+86.10.5817.6000
Fax: +86 10 8518 9299

Berlin
Markgrafenstraße 42
10117 Berlin, Germany
+49.(0)30.220.029.0
Fax +49.(0)30.220.029.499

Boston
State Street Financial Center
One Lincoln Street
Boston, Massachusetts 02111
+1.617.261.3100
Fax +1.617.261.3175

Brussels
The View Building
Rue de l'Industrie 26/38
1040 Brussels, Belgium
+32.(0)2.336.1900
Fax: +32.(0)2.336.1901

Charleston
4000 Faber Place Drive
Suite 300
North Charleston, SC 29405
+1.843.323.4240
Fax +1.843.628.4823

Charlotte
214 North Tryon Street
Hearst Tower, 47th Floor
Charlotte, North Carolina 28202
+1.704.331.7400
Fax +1.704.331.7598

Chicago
70 West Madison Street
Suite 3100
Chicago, Illinois 60602
+1.312.372.1121
Fax +1.312.827.8000

Dallas
1717 Main Street, Suite 2800
Dallas, Texas 75201
+1.214.939.5500
Fax +1.214.939.5849

Doha
Qatar Financial Centre Branch
9th Floor, Al Fardan Office Tower
P.O. Box 31316
West Bay, Doha, Qatar
+974.4410.1863
Fax +974.4410.1864

Dubai
Currency House, Level 4
Dubai International
Financial Centre
P.O. Box 506826
Dubai, United Arab Emirates
+971.4.427.2700
Fax +971.4.447.5225

Fort Worth
D.R. Horton Tower
301 Commerce, Suite 3000
Fort Worth, Texas 76102
+1.817.347.5270
Fax +1.817.347.5299

Frankfurt
Opernturm
Bockenheimer Landstraße 2-4
60306 Frankfurt am Main, Germany
+49.(0)69.945.196.0
Fax +49.(0)69.945.196.499

Harrisburg
17 North Second Street
18th Floor
Harrisburg, Pennsylvania 17101
+1.717.231.4500
Fax +1.717.231.4501

Hong Kong
44th Floor, Edinburgh Tower
The Landmark
15 Queen's Road Central
Hong Kong
+852 2230 3500
Fax: +852 2511 9515

London
One New Change
London EC4M 9AF
England
+44.(0)20.7648.9000
Fax: +44.(0)20.7648.9001

Los Angeles
10100 Santa Monica Boulevard
7th Floor
Los Angeles, California 90067
+1.310.552.5000
Fax +1.310.552.5001

Miami
Southeast Financial Center
Suite 3900
200 South Biscayne Boulevard
Miami, Florida 33131
+1.305.539.3300
Fax +1.305.358.7095

Moscow
Lesnaya Street, 5
Building B, 4th Floor
Moscow 125047, Russia
+7.495.643.1700
Fax +7.495.643.1701

Newark
One Newark Center, Tenth Floor
Newark, New Jersey 07102
+1.973.848.4000
Fax +1.973.848.4001

New York
599 Lexington Avenue
New York, New York 10022
+1.212.536.3900
Fax +1.212.536.3901

Orange County
1900 Main Street, Suite 600
Irvine, California 92614
+1.949.253.0900
Fax +1.949.253.0902

Palo Alto
630 Hansen Way
Palo Alto, California 94304
+1.650.798.6700
Fax +1.650.798.6701

Paris
Avocats à la Cour
116 avenue des Champs-Elysées
75008 Paris, France
+33.(0)1.58.44.15.00
Fax: +33.(0)1.58.44.15.01

Pittsburgh
K&L Gates Center
210 Sixth Avenue
Pittsburgh, Pennsylvania 15222
+1.412.355.6500
Fax +1.412.355.6501

Portland
222 SW Columbia Street,
Suite 1400
Portland, Oregon 97201
+1.503.228.3200
Fax +1.503.248.9085

Raleigh
4350 Lassiter at North Hills Ave.,
Suite 300
Raleigh, North Carolina 27609
+1.919.743.7300
Fax +1.919.743.7358

Research Triangle Park
430 Davis Drive, Suite 400
Morrisville, North Carolina 27560
+1.919.466.1190
Fax +1.919.831.7040

San Diego
3580 Carmel Mountain Road
Suite 200
San Diego, California 92130
+1.858.509.7400
Fax +1.858.509.7466

San Francisco
Four Embarcadero Center
Suite 1200
San Francisco, California 94111
+1.415.882.8200
Fax +1.415.882.8220

São Paulo
Rua Iguatemi 151, conjunto 281
Ed. Spazio Faria Lima
São Paulo, SP 01451-011, Brazil
+55.(0)11.3704.5700
Fax +55.(0)11.3958.0611

Seattle
925 Fourth Avenue, Suite 2900
Seattle, Washington 98104
+1.206.623.7580
Fax +1.206.623.7022

Shanghai
Suite 3708, Park Place
1601 Nanjing Road West
Jing An District
Shanghai 200040, China
+86.21.2211.2000
Fax +86.21.3251.8918

Singapore
10 Collyer Quay
#37-01 Ocean Financial Center
Singapore, 049315
+65.6507.8100
Fax +65.6507.8111

Spokane
618 West Riverside, Suite 300
Spokane, Washington 99201
+1.509.624.2100
Fax +1.509.456.0146

Taipei
30/F, 95 Tun Hwa S. Road
Sec. 2
Taipei 106, Taiwan
+886.2.2326.5188
Fax +886.2.2325.5838

Tokyo
Kasumigaseki Common Gate
West Tower 35F
3-2-1 Kasumigaseki, Chiyoda-ku
Tokyo 100-0013
Japan
+81.3.6205.3600
Fax: +81.3.3597.6421

Warsaw
Al. Jana Pawla II 25
00 854 Warsaw, Poland
+48 22 653 4200
Fax: +48 22 653 4250

Washington, D.C.
1601 K Street, NW
Washington, D.C. 20006
+1.202.778.9000
Fax +1.202.778.9100

Author List

Dr. Martin von Albrecht (Berlin)
martin.albrecht@klgates.com

Rosemary Alito (Newark)
rosemary.alito@klgates.com

Diane E. Ambler
(Washington, D.C.)
diane.ambler@klgates.com

Sara Aparicio Hill (Brussels)
sara.apariciohill@klgates.com

Claude-Étienne Armingaud (Paris)
clawdey.armingaud@klgates.com

Mary Burke Baker
(Washington, D.C.)
mary.baker@klgates.com

George P. Barbatsuly (Newark)
george.barbatsuly@klgates.com

Neil A. Baylis (London)
neil.baylis@klgates.com

David L. Beam (Washington, D.C.)
david.beam@klgates.com

Daniela Bohn (Frankfurt)
daniela.bohn@klgates.com

Dr. Tobias Bosch (Berlin)
tobias.bosch@klgates.com

Dr. Markus Brock (Berlin)
markus.brock@klgates.com

Paul Callegari (London)
paul.callegari@klgates.com

David T. Case (Washington D.C.)
david.case@klgates.com

Sebastian A. Charles (London)
sebastian.charles@klgates.com

Piers Coleman (London)
piers.coleman@klgates.com

Daniel F. C. Crowley
(Washington, D.C.)
dan.crowley@klgates.com

Andrew R. Danson (London)
andrew.danson@klgates.com

Raminta Dereskeviciute (London)
raminta.dereskeviciute@klgates.com

Flavia Distefano (Brussels)
flavia.distefano@klgates.com

Etienne Drouard (Paris)
etienne.drouard@klgates.com

Vanessa C. Edwards
(London, Brussels)
vanessa.edwards@klgates.com

Michael W. Evans
(Washington, D.C.)
michael.evans@klgates.com

Valentina Farle (Frankfurt)
valentina.farle@klgates.com

Brendon P. Fowler
(Washington D.C.)
brendon.fowler@klgates.com

Jacqueline Fu (Taipei)
jacqueline.fu@klgates.com

Daniel J. Gerkin
(Washington, D.C.)
daniel.gerkin@klgates.com

Kenneth L. Glazer
(Washington, D.C.)
ken.glazer@klgates.com

Stephen C. Glazier
(Washington, D.C.)
stephen.glazier@klgates.com

John B. Godfrey
(Washington, D.C.)
john.godfrey@klgates.com

Ruth E. Granfors (Harrisburg)
ruth.granfors@klgates.com

Robert Hadley (London)
robert.hadley@klgates.com

Dr. Friedrich Ludwig Hausmann
(Berlin)
friedrich.hausmann@klgates.com

Iris He (Beijing)
iris.he@klgates.com

Patrick G. Heck
(Washington, D.C.)
patrick.heck@klgates.com

Bruce J. Heiman
(Washington, D.C.)
bruce.heiman@klgates.com

William H. Hyatt, Jr. (Newark)
william.hyatt@klgates.com

Siobhan Kahmann (Brussels)
siobhan.kahmann@klgates.com

Chase D. Kaniecki
(Washington, D.C.)
chase.kaniecki@klgates.com

Steven M. Kaplan
(Washington, D.C.)
steven.kaplan@klgates.com

Sabine F. Konrad (Frankfurt)
sabine.konrad@klgates.com

Charles R. Mills (Washington, D.C.)
charles.mills@klgates.com

Matt T. Morley (Washington, D.C.)
matt.morley@klgates.com

Dr. Annette Mutschler-Siebert, M.Jur.
(Berlin)
annette.mutschler-siebert@klgates.com

Lauren N. Norris (Chicago)
lauren.norris@klgates.com

Cindy L. O'Malley
(Washington, D.C.)
cindy.omalley@klgates.com

Karishma Shah Page
(Washington, D.C.)
karishma.page@klgates.com

Lawrence B. Patent
(Washington, D.C.)
lawrence.patent@klgates.com

Gordon F. Peery (Orange County)
gordon.peery@klgates.com

Mark D. Perlow (San Francisco)
mark.perlow@klgates.com

Warren L. Phelops (London)
warren.phelops@klgates.com

David E. Pickle (Washington, D.C.)
david.pickle@klgates.com

William M. Reichert (Moscow)
william.reichert@klgates.com

Cliff L. Rothenstein
(Washington, D.C.)
cliff.rothenstein@klgates.com

Anna V. Ryabtseva
(Moscow)
anna.ryabtseva@klgates.com

Brian F. Saulnier
(Pittsburgh, Dubai)
brian.saulnier@klgates.com

Rainer Schmitt (Frankfurt)
rainer.schmitt@klgates.com

Dr. Mathias Schulze Steinen, LL.M.
(Frankfurt)
mathias.schulze-steinen@klgates.com

Patricia C. Shea (Harrisburg)
patricia.shea@klgates.com

Yujing Shu (Beijing)
yujing.shu@klgates.com

Donald W. Smith
(Washington, D.C.)
donald.smith@klgates.com

Amy L. Sommers (Shanghai)
amy.sommers@klgates.com

Alexandros Stamoulis
(Washington, D.C.)
aleko.stamoulis@klgates.com

Paul D. Thompson (London)
paul.thompson@klgates.com

Philip Torbøl (Brussels)
philip.torbol@klgates.com

Christopher Tung (Hong Kong)
christopher.tung@klgates.com

Jerome J. Zaucha
(Washington, D.C.)
jerome.zaucha@klgates.com

David D. Zhang (Shanghai)
david.zhang@klgates.com

Editors

Diane E. Ambler
(Washington, D.C.)
diane.ambler@klgates.com

Michael J. Missal
(Washington, D.C.)
michael.missal@klgates.com

Matt T. Morley
(Washington, D.C.)
matt.morley@klgates.com

Mark D. Perlow
(San Francisco)
mark.perlow@klgates.com

K&L GATES

Anchorage Austin Beijing Berlin Boston Brussels Charleston Charlotte Chicago Dallas Doha Dubai Fort Worth Frankfurt Harrisburg Hong Kong London Los Angeles Miami Moscow Newark New York Orange County Palo Alto Paris Pittsburgh Portland Raleigh Research Triangle Park San Diego San Francisco São Paulo Seattle Shanghai Singapore Spokane Taipei Tokyo Warsaw Washington, D.C.

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